

### **DETAILED ACTION**

Claims 34, 36, 42, 45, 47-54, and 60-68 are pending in the instant application. Claims 47-52 and 63-68 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to non-elected subject matter. The withdrawn subject matter is patentably distinct from the elected subject matter as it differs in structure and element and would require separate search considerations. In addition, a reference which anticipates one group would not render obvious the other. Claims 34, 36, 45, 53, 54, and 60-62 are rejected. Claim 42 is objected.

### ***Information Disclosure Statements***

The information disclosure statements filed on July 21, 2006 and November 24, 2008 were considered and signed copies of form 1449 are enclosed herewith.

### ***Election/Restrictions***

Applicants' election without traverse of Group I, claims 34, 36, 42, 45, 53, 54, and 60-62, and the species 2-Hydroxy-3-(5-([4-(2-morpholin-4-ylethyl)piperazin-1-yl]sulfonyl)pyridin-2-yl)-1H-indole-6-carbonitrile hydrochloride in the response filed on March 19, 2009 has been acknowledged.

Upon further consideration, the requirement to elect a single disclosed species has been withdrawn (i.e., the subject matter of Group I or claims 34, 36, 42, 45, 53, 54, and 60-62 have been searched and examined in their entirety). The restriction requirement is still deemed proper and is maintained.

### ***Claim Rejections - 35 USC § 102***

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the

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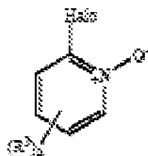
applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 34, 36, 45, 53, 54, and 60-62 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent No. 7,399,780 which has benefit of WO 03/082853, filed on March 28, 2003, because the subject matter used to make the rejection is appropriately supported in the relied upon earlier-filed application's disclosure.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

US Patent No. 7,399,780 discloses compounds of formula Ia which are used in pharmaceutical formulations (i.e., abstract), such as 2-Hydroxy-3-{5-[(4-methylpiperazin-1-yl)sulfonyl]pyridin-2-yl}-1H-indole-5-carbonitrile (i.e., claim 6, column 65, lines 34 and 35) which anticipates a compound of formula Ia of the instant claims and is specifically listed as the first compound in claim 61 of the instant claims. The process of claim 53 of the instant claims is anticipated by the reaction disclosed in US Patent No. 7,399,780 (i.e., column 20) wherein R3 can be C0-6alkyl(SO2)NR4R5 or (SO2)NR4R5 and R2 can be C0-6alkylcyano or cyano (i.e., column 3). Also anticipated by US Patent No. 7,399,780 (i.e., column 19) is the reaction of claim 54 of the instant claims. U.S. Patent No. 7,399,780 discloses that a compound of formula (XXV) can be a

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compound of formula (i.e., column 24) and R3 can be C0-6alkyl(SO2)NR4R5 or (SO2)NR4R5.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 34, 36, 45, and 60-62 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over (at least) claims 5-8 and 15 of U.S. Patent No. 7,399,780. Although the conflicting claims are not identical, they are not patentably distinct from each other for the reasons given below.

U.S. Patent No. 7,399,780 discloses compounds and pharmaceutical formulations with the same formula Ia that is disclosed in the instant application. Some

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of the same specific compounds which are disclosed in the instant claims are disclosed in U.S. Patent No. 7,399,780. For example, compound 2-Hydroxy-3-{5-[(4-methylpiperazin-1-yl)sulfonyl]pyridin-2-yl}-1H-indole-5-carbonitrile is disclosed in claim 6 of U.S. Patent No. 7,399,780 (column 65, lines 34 and 35) and this compound is also disclosed as the first compound listed in claim 61 of the instant claims. Also, some of the compounds listed in U.S. Patent No. 7,399,780 are anticipated by formula Ia of the instant claims (i.e., compound 2-Hydroxy-3-[5-(morpholin-4-ylsulfonyl)pyridin-2-yl]-1H-indole-5-carbonitrile or the last compound listed in claim 5 of U.S. Patent No. 7,399,780). MPEP § 2144.08.11.A.4(c) states "... consider teachings of a preferred species within the genus. If such a species is structurally similar to that claimed, its disclosure may motivate one of ordinary skill in the art to choose the claimed species or subgenus from the genus, based on the reasonable expectation that structurally similar species usually have similar properties". This is the "Genus- Species Guidelines" for examination based on 35 USC 103 and an analogous guideline was followed here for the analysis of obviousness-type double patenting. Therefore, it would have been obvious to one of ordinary skill in the art to make (at least some of) the compounds and compositions of the instant application given U.S. Patent No. 7,399,780.

### ***Claim Objections***

Claim 42 is objected for depending on a previous rejected base claim.

### ***Conclusion***

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to KRISTIN BIANCHI whose telephone number is (571)270-5232. The examiner can normally be reached on Mon-Fri 7am-3:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kamal A Saeed/  
Primary Examiner, Art Unit 1626

Kristin Bianchi  
Examiner  
Art Unit 1626

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